STATE MEDICAID DUR BOARD MEETING

THURSDAY, January 14, 2010
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

MINUTES

Board Members Present:

Kathy Goodfellow, R.Ph.
Brad Hare, M.D.
Wilhelm Lehmann, M.D.
Dominic DeRose, R.Ph.
Cris Cowley, M.D.
Tony Dalpiaz, PharmD.
Peter Knudson, D.D.S.
Joseph Miner, M.D.
Bradley Pace, PA-C

Board Members Excused:

Neal Catalano, R.Ph.
Joseph Yau, M.D.
Mark Balk, PharmD.

Dept. of Health/Div. of Health Care Financing Staff Present:

Lisa Hulbert, R.Ph.
Jennifer Zeleny, CPhT, MPH
Amber Kelly, R.N.
Marisha Kissel, R.N.
Rick Sorenson, R.N.
Tim Morley, R.Ph.
Merelynn Berrett, R.N.

Other Individuals Present:

Paul Lakore, OMJ
J. Sonkiss, U of U
Lori Howarth, Bayer
John Stockton, Genentech
Cap Ferry, LEC
M. McAsom
Vicki Winkel, U of U
Lisa Gilliam, Reckitt Binckiser
C. Howell, U of U
Duk Pham, M.D., U of U

Meeting conducted by: Wilhelm Lehmann, M.D.

1 Review and Approval of Minutes: Dominic DeRose moved to approve the minutes. Dr. Hare seconded the motion. The motion was approved with unanimous votes by Kathy Goodfellow, Dr. Hare, Dominic DeRose, Dr. Lehmann, Brad Pace, Tony Dalpiaz, Dr. Miner, and Dr. Cowley.

2 PDL Update: Duane Parke addressed the Board. Medicaid is still working on getting the 2010 contracts to the drug companies. Some changes will be made in 2010, particularly to the PPI class. Duane thanked the drug manufacturers for their patience, as 2010 contracts are continuing to come out. The P&T Committee recently approved the oral fluroquinolones, and the PDL will be published shortly.

3 Suboxone: Lisa Hulbert addressed the Board. At the close of the last meeting, the Board had asked Lisa to provide draft language for proposed changes to the Suboxone PA. She provided that draft to the Board, as well as utilization information on Suboxone and how the new PA has effected utilization.

The Board asked how it would be demonstrated that the patient would be enrolled in a 12-step treatment program. Lisa stated that it would not be possible for Medicaid to get a court order or enforce that. The prescriber would be asked to chart that a 12-step program was discussed and that the patient has chosen a program.

The Board asked if the rest of the information in the new PA would be collected through chart notes. Lisa indicated that would be the case.

Dr. Miner thought that the Board had discussed the need for long-term availability of Suboxone to some patients. The proposed PA revision does not provide for this. Lisa explained that the State Plan does not provide for maintenance therapy for drug addiction, only for withdrawal. Dr. Miner indicated that methadone therapy for addiction can go on for years. Lisa stated that methadone clinics are paid at a capitated daily rate that includes management as well as cost of the medication. At the higher doses, the rate does not even cover the cost of the medication, so it is debatable whether or not Medicaid is actually paying for the drug. The agency is not debating the usefulness of long-term therapy in some clients, but the State Plan only allows for withdrawal and not maintenance. The Board asked if it could be changed by the DUR Board or at the Legislative level. It may be changeable.

Dr. Lehmann asked how long the other states will cover the Suboxone. There are some states that have not taken action with Suboxone at all, but may be in the future since the inappropriate use of Suboxone will be discussed at a national meeting in February. Other states utilize quantity limits, and some have PAs. It varies by state.

Rick Sorenson asked if the maximum 24 weeks of therapy was based on calendar year or rolling year. It is based on rolling year.

The Board asked if the Federal government will only pay for 6 months of therapy per year. Lisa stated that the contract that Utah has with the Federal government only allows for withdrawal. Recommending six months for Suboxone was an attempt to make the PA criteria consistent with other PAs for drugs that are used to treat addiction and withdrawal.

Dr. Hare stated that a patient can be withdrawn from opioids in a week. Technically, if the Board is to consider withdrawal, the Board does not need to discuss this. However, withdrawal without treatment has very poor outcomes. Better outcomes occur when a patient is treated and maintained over some period of time. The definitions in this area are fuzzy. He feels that the guidelines that are set up for the period of time under consideration are appropriate, but feels that the six months are not going to work for some patients. He wanted to know if there was a way to build in an exception. Dr. Miner agreed, and felt that it would be a wasted six months if the patient were to go off the medication and relapse.

Duane asked if dose-creep occurs with this drug. Dr. Howell stated that 90-95% of the brain receptors are occupied at 16mg per day. In her practice, she has only about 2-3 patients at 32mg per day, and some on much less. The average is between 8-16mg per day. Duane asked if the costs were comparable to other long-acting opioids. The information had been provided to the DUR Board.

Dr. Miner stated that if methadone were covered for maintenance, then it would be prudent to have a fail-first policy with methadone before approving Suboxone for maintenance. However, if methadone is not even covered for maintenance, then the DUR Board should go back to looking at the criteria that is before them for withdrawal.

Dr. Hare asked Dr. Howell if a six-month therapy would serve most Suboxone patients. She stated that it would not. For some people who are early in their addiction careers, they might be able to get on it and taper off and do psychosocial treatment. The preponderance of the evidence says that patients need maintenance therapy. This does not mean that patients have to be on it forever. The difference between buprenorphine and methadone is that she thinks that there is more healing of the brain receptor system that happens over a period of 3-5 years.

Dr. Sonkiss felt that is was inappropriate to focus on direct cost versus indirect cost. A patient on Suboxone is much more able to process information than a patient on methadone, and the long term outcomes are better. There is no direct evidence to support that statement, but all clinicians who deal with Suboxone know that. Dr. Howell added that there is also less mortality and morbidity with Suboxone than with methadone.

Dr. Lehmann asked the Board if they have any issues with the criteria under consideration. Dr. Miner stated that if Medicaid cannot cover long term treatment, we should go back to the original eight-week approval. Rick stated that the prior criteria for eight weeks was revolving, the way that it was written, and that treatment could go on for years if the doctor provided a letter every eight weeks. The problem was that doctors would send the same form letters every eight weeks, and did not provide good evidence to justify continuing the PA.

Lisa added that if patients have a diagnosis of chronic pain as well as substance abuse, they should be shifted to a drug that is indicated for pain.

Kathy Goodfellow stated that the overwhelming consideration seems to be cost. If that was not a factor, Medicaid would provide the drug ongoing. Also, the PA should state specifically that it cannot be paid for chronic pain.

Dr. Lehmann and Lisa clarified that the consideration is also the State Plan that enables Medicaid to get a 75% federal match. Dr. Miner stated that there has to be a way to modify the State Plan, and Medicaid should look into modifying.

Dr. Howell stated that if the ultimate goal is to get patients off the drug, long-term therapy could be viewed as a long-term withdrawal process. Most patients will want to be off medication, but it is not realistic to do this in six months because the brain needs longer to

heal. A six month authorization would be disruptive. Private sector insurance does a review every 4-6 months, but does not withdraw therapy. Lisa stated that Medicaid has seen claims data indicating that many patients are put on extremely high doses, and left on the high doses for years. Many of these patients are also being given other opioids narcotics, often from the same physician.

Tim stated that the Board needs to remember that the goal is to determine a benefit. The Board is not dictating how it is going to be used, since that rests with the physician. The Board needs to determine a benefit under the parameters that restrict Medicaid.

The Board asked if there is someone within Medicaid that can amend the State Plan. Tim stated that he is attending a national DUR meeting, where all 50 states and CMS will be represented. Suboxone will be under discussion there. It was recommended that Medicaid investigate the possibility of extending the Prior Authorization if Utah Medicaid can amend the contract with CMS.

Dr. Hare stated that these criteria are probably the best the Board will be able to do now and in the near future. The Board's feelings should be conveyed to whoever is able to make a change to the State Plan, and that the State Plan should be brought in line with best clinical practice. In the meanwhile, the proposed criteria are the best that they can do.

Dr. Hare moved that the criteria are accepted as proposed, with the recommendation that Medicaid initiate the process for amending the State Plan to allow for long-term treatment of opioid dependency. Kathy Goodfellow seconded the motion. The motion was approved with unanimous votes by Kathy Goodfellow, Dr. Hare, Dominic DeRose, Dr. Lehmann, Brad Pace, Tony Dalpiaz, Dr. Miner, Dr. Knudson, and Dr. Cowley.

Dr. Howell asked if she could, as a clinician, request another six months at the end of the initial six months. Lisa advised her that she may always request that by appeal to the DUR Board.

Dr. Lehmann stated that the Board should re-examine the criteria within six months to reconsider whether or not it is feasible to approve longer-term therapy. The Board members wanted it to be on record that they feel it is appropriate to have ongoing therapy for a longer period of time than six months.

4 Sabril: Lisa Hulbert addressed the Board. Sabril is an oral tablet indicated for complex partial seizures. It is not a first-line agent, and causes bilateral visual field reduction in up to 30% of patients, that is permanent. It can also cause loss of visual acuity. Because of this, patients and physicians must be enrolled in a program to receive this medication. It has other significant side-effects that were provided to the Board. Proposed PA criteria were presented to the Board.

The Board questioned if it was also appropriate to include an indication for infantile spasms, which is not FDA approved. The Board members concluded that treatment of infantile spasms should be by petition to the Board. Pregnancy screening should also be required,

due to tetratogenicity.

Dr. Miner moved to approve the proposed PA criteria as amended. Kathy Goodfellow seconded the motion. The motion was approved with unanimous votes by Kathy Goodfellow, Dr. Hare, Dominic DeRose, Dr. Lehmann, Brad Pace, Tony Dalpiaz, Dr. Miner, Dr. Knudson, and Dr. Cowley.

5 Embeda: Lisa Hulbert addressed the Board. Embeda is a combination product of morphine sulfate and naltrexone. It comes in an oral capsule in six different strengths. The DUR Board members were provided handouts describing the strengths and indications. Proposed PA criteria were provided to the Board.

Kathy Goodfellow pointed out the statement in the package insert that states that there is no evidence that the naltrexone in Embeda reduces the abuse liability.

Dr. Hare stated that there is a big movement to try to avoid diversion and misuse of opioids prescribed legitimately for chronic pain. There are websites that inform people how to abuse prescription narcotics. This drug is a first step towards avoiding collateral damage associated with narcotics, even though morphine is one of the less frequently abused medications. In theory, this should prevent abuse, even if it has not been proven. Similar things will probably be seen in the future with other drugs, and the outcome should be greater safety. At some point, practitioners will be compelled to switch over to these other products, because there is no way to tell whose prescription will end up diverted.

Dr. Miner asked how prescriptions are handled for people who have been on the medication when a new PA is put into place. Lisa stated that all new PAs have to go through the process of 90-days notice before they are implemented. Embeda was brought to the DUR Board shortly after being introduced to the market.

Dr. Miner moved to accept the PA criteria as proposed. Tony Dalpiaz seconded the motion. The motion was approved with unanimous votes by Kathy Goodfellow, Dr. Hare, Dominic DeRose, Dr. Lehmann, Brad Pace, Tony Dalpiaz, Dr. Miner, Dr. Knudson, and Dr. Cowley.

The DUR Board Prior Approval Subcommittee to considered 5 petitions this month. 3 were approved.

Minutes prepared by Jennifer Zeleny